IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

STEPHANIE IDEUS, Plaintiff, vs. TEVA PHARMACEUTICALS USA, INC. and TEVA WOMEN'S HEALTH, INC., Defendants.	4:16-CV-3086 MEMORANDUM AND ORDER

This matter is before the Court on the defendants' motion for summary judgment (filing 81). That motion will be granted and the plaintiff's complaint will be dismissed.

BACKGROUND

The facts of this case are set forth in this Court's December 12, 2017 Memorandum and Order. Filing 56. Briefly summarized, the plaintiff, Stephanie Ideus, received the birth control ParaGard T380 Intrauterine Copper Contraceptive. Filing 81 at 6. Four years later, as her physician was removing the ParaGard, a piece of the device broke off and embedded in the myometrium of the plaintiff's uterine wall. Filing 81 at 7. The broken piece was surgically removed in 2016. Filing 81 at 7.

Ideus claims she was not adequately warned of the possible risks associated with ParaGard. *See* filing 96 at 3. To support that contention, Ideus points to an "Information for Patients" brochure she received before the device was implanted, and to the product's package insert, which contains prescribing information for treating physicians. *See* filing 96 at 3. Both sets of materials, she alleges, lack any warning that the ParaGard "could break during removal,"

or that smaller pieces of the device (as opposed to the device as a whole) could separate and become embedded "deep in the uterus[.]" Filing 96 at 6. Ideus has sued the manufacturers of the device, Teva Pharmaceuticals and Teva Women's Health (collectively, Teva), for allegedly failing to provide adequate warnings. *See* filing 21 at 6-17. Teva moves for summary judgment, and for the reason set forth below, that motion will be granted.

STANDARD OF REVIEW

Summary judgment is proper if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). The movant bears the initial responsibility of informing the Court of the basis for the motion, and must identify those portions of the record which the movant believes demonstrate the absence of a genuine issue of material fact. *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042 (8th Cir. 2011) (en banc). If the movant does so, the nonmovant must respond by submitting evidentiary materials that set out specific facts showing that there is a genuine issue for trial. *Id.*

On a motion for summary judgment, facts must be viewed in the light most favorable to the nonmoving party only if there is a genuine dispute as to those facts. *Id.* Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the evidence are jury functions, not those of a judge. *Id.* But the nonmovant must do more than simply show that there is some metaphysical doubt as to the material facts. *Id.* In order to show that disputed facts are material, the party opposing summary judgment must cite to the relevant substantive law in identifying facts that might affect the outcome of the suit. *Quinn v. St. Louis County*, 653 F.3d 745, 751 (8th Cir. 2011). The mere existence of a scintilla of evidence in support of the nonmovant's position will be insufficient; there must be evidence on which the

jury could conceivably find for the nonmovant. *Barber v. C1 Truck Driver Training, LLC*, 656 F.3d 782, 791-92 (8th Cir. 2011). Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial. *Torgerson*, 643 F.3d at 1042.

DISCUSSION

Ideus' sole remaining claim is that Teva failed to adequately warn her of the risks associated with ParaGard.[1] Under Nebraska law, a manufacturer is subject to liability for failing either to warn or adequately to warn about a risk or hazard inherent in the way a product is designed that is related to the intended uses as well as the reasonably foreseeable uses that may be made of the products it sells. *Freeman v. Hoffman–La Roche, Inc.*, 618 N.W.2d 827, 841 (Neb. 2000); *Rahmig v. Mosley Machinery Co.*, 412 N.W.2d 56 (Neb. 1987). In other words, a manufacturer's duty to produce a safe product, with appropriate warnings and instructions when necessary, is no different from the responsibility each of us bears to exercise due care to avoid unreasonable risks of harm to others. *Freeman*, 618 N.W. 2d at 841.

According to Ideus, Teva breached this duty. More specifically, Ideus claims that neither the warning given to her prescribing physician (*i.e.*, the package insert), nor the information received directly by Ideus (*i.e.*, the patient brochure) adequately, if at all, warned of the risk of "embedment or breakage." Filing 57 at 5-6. Teva, on the other hand, argues that the only relevant warning label, the one in the package insert, was adequate as a matter of law. *See* filing 81 at 5. Alternatively, Teva contends that Ideus' claim is preempted by federal

[1] As previously noted, Ideus voluntarily dismissed her claims for manufacturing defect, design defect, and fraud. Filing 50 at 1.

law because it could not unilaterally change ParaGard's warning labels without violating federal regulations. Filing 81 at 17-23.

The Court need not address Teva's latter contention. Even assuming (without deciding) that Ideus' failure-to-warn claim is not preempted, that claim fails nonetheless. But before explaining why that is true, the Court must take a brief detour though the history and applicability of the doctrine underlying much of the parties' dispute: the learned intermediary doctrine.

The learned intermediary doctrine is an exception to the general rule that a manufacturer or seller is subject to liability for failing either to warn or adequately to warn about a risk or hazard inherent in the way a product is designed or reasonably foreseeable uses that may be made of the products it sells. *Freeman*, 618 N.W.2d at 841. In essence, the doctrine provides that when prescription drugs are involved, a manufacturers' duty to warn is discharged so long as the manufacturer provided adequate warnings to a patient's prescribing health-care provider. *Id*.

But not all courts agree that the learned intermediary doctrine applies to prescription contraceptives. Some courts distinguish contraceptives from other prescription drugs and decline to apply the learned intermediary doctrine. *MacDonald v. Ortho Pharm. Corp*, 475 N.E.2d 65 (Mass. 1985); *Stephens v. G.D. Searle*, 602 F. Supp. 379 (E.D. Mich. 1985). In those jurisdictions, the manufacturer has a duty to directly warn a consumer about the risks of the product. Other courts, however, do not treat contraceptives differently. *See West v. Searle Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Cobb v. Syntex Laboratories*, 444 So. 2d 203 (La. App. 1983); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982); *Seley v. Searle & Co.*, 423 N.E.2d 831 (Ohio 1981); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541 (Ind. App. 1979); *Terhune*, 577 P.2d at 978; *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974);

Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449 (Pa. Super. 1973). And in those jurisdictions, the learned intermediary doctrine applies to all prescription drugs or devices—including contraceptives.

Although the Nebraska Supreme Court has adopted the learned intermediary doctrine, *Freeman*, 618 N.W.2d at 571, it has yet to address whether it would recognize an exception to the learned intermediary doctrine for prescription contraceptives. So, this Court is tasked with predicting whether the Nebraska Supreme Court would apply the learned intermediary doctrine to contraceptives.

According to Teva, the Nebraska Supreme Court would apply the learned intermediary doctrine. In support of that argument, Teva points to the rationale behind the learned intermediary doctrine: "the physician, as the prescriber of a drug, is in the best position to give a highly individualized warning to a patient based on the physician's knowledge of the patient and the inherent risks of the drug." *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1305 (D. Minn. 1988). And because contraceptives are prescribed by physicians, Teva argues that the doctrine necessarily applies. *See* filing 81 at 27-18. Ideus, however, claims that the Nebraska Supreme Court would distinguish between contraceptives and other prescription drugs. This is true, Ideus argues, because contraceptives are, by their very nature, distinguishable from average prescription drugs. *See* filing 90 at 13-15.

This Court agrees with Teva. It is true that Ideus' view is consistent with courts in Massachusetts and Michigan, *see MacDonald*, 475 N.E.2d at 66; *Stephens*, 602 F. Supp. at 380. And Ideus view is also consistent with the Eighth Circuit's decision predicting Arkansas law in *Hill v. Searle Labs., a Div. of Searle Pharm., Inc.*—a decision Ideus relies on extensively to support why, in her view, Nebraska would create an exception to the learned intermediary

doctrine for contraceptives. 884 F.2d 1064, 1070 (8th Cir. 1989). But after *Hill* was decided, the Arkansas Supreme Court determined to the contrary that the learned intermediary doctrine *does* apply to contraceptives. *West v. Searle Co.*, 806 S.W.2d 608, 614 (Ark. 1991). And just as important, the factors articulated in *Hill* for a modified approach to the learned intermediary doctrine, if applied in this case, counsel in favor of applying the doctrine.

In *Hill*, the plaintiff sued the manufacturer of her copper IUD after the product perforated her uterus and partially imbedded itself in her uterine wall. *Id.* The district court determined that the plaintiff could not recover because her doctor had been given adequate warnings, severing the causal connection under the learned intermediary doctrine. *Id.* at 1071. But a divided panel of the Eighth Circuit predicted that the Arkansas Supreme Court would distinguish contraceptives from other prescription drug products, and would instead require "either a warning—meaningful and complete so as to be understood by the recipient—or an individualized medical judgment that this treatment or medication is necessary and desirable for this patient." *Id.* at 1071. And the Court of Appeals concluded that IUD prescription is not the result of "individualized medical judgment." *See id.*

In reaching that conclusion, the Eighth Circuit focused on several factors which, in its view, distinguished contraceptive prescriptions from other prescription medication. First, the court opined that birth control is a private matter often dependent on factors such as "effectiveness, convenience or cost, rather than medical necessity." *Id.* Second, the court focused on the manufacturer's decision to market directly to the consumer with the idea of convincing women to choose the IUD. *Id.* Third, the court thought that beyond the initial contact, there is little to no contact between physician and patient regarding the choice and the risks of using IUD's. *Id.* And finally, the court

believed that contraceptives are given more often than not under clinic-type conditions where physician-patient contact is limited. *Id.* Together, those factors, the court said, supported the plaintiff's position that contraceptives stand apart from other prescription drugs rendering the learned intermediary doctrine inapplicable.

But—to the extent that the Eighth Circuit's assumptions regarding how birth control was prescribed in 1991 remain vital over 25 years later—the majority of the factors relied on in *Hill* are absent here. First, although Ideus' IUD was placed under "clinic-like" conditions, there is no evidence to suggest that physician-patient contact was particularly limited in this case. *Cf. Hill*, 884 F.2d at 1070. To the contrary. Ideus testified that she "regularly" visited her prescribing physician over the years. Filing 95 at 19. During her annual visit in 2011, Ideus told her doctor that she wanted to use a long-term contraceptive. Filing 95 at 20. After Ideus and her physician "discussed [] what [her] options were," Ideus was given literature on ParaGard. Filing 95 at 20. On a later date, Ideus' ParaGard was inserted by her physician. Filing 95 at 20. So, unlike *Hill*, there was actually significant physician-patient contact between Ideus and her prescribing physician. *Cf. Hill*, 884 F.2d at 1070.

Second, there is no record evidence suggesting that Teva actually marketed directly to consumers near the time Ideus had ParaGard inserted.[2] Filing 97 at 6; *see also* filing 91-2,91-3. Nor is there any evidence that Ideus even saw a ParaGard advertisement—much less relied on one—in choosing

[2] The only evidence that ParaGard was marketed directly to consumers is based on a 2016 Cosmopolitan magazine advertisement from nearly five years after Ideus' ParaGard was placed. Filing 91-3 at 1-3.

ParaGard as her preferred method of contraception.[3] *See* filing 97 at 6; *see also* filing 91-2,91-3. To the contrary, the only evidence before the Court is that Ideus relied on the advice and literature given to her by her prescribing doctor in choosing ParaGard—a fact that actually weighs in favor of applying the learned intermediary doctrine, not against it. Filing 95 at 20-21.

And that brings the Court to the final distinguishing factor emphasized by the *Hill* court: the patient's undoubted right to choose her own contraception. *Cf. Hill*, 884 F.2d at 1070. Although the Court agrees that factors such as "effectiveness, convenience or cost" might be considered by a patient when choosing among suggested contraception, those are not the factors Ideus focused on in this case. *Cf. id.* at 1070. Instead, Ideus testified that in making her decision, at the forefront of her considerations were factors such as whether the contraceptive "was hormone free . . . reliable . . . and would last long term." Filing 95 at 20.

And determining what contraceptive fits that particular criteria necessarily requires the knowledge and advice of a physician. Thus, the Court sees no reason to distinguish between a patient's final choice to use a particular contraceptive and a patient's final decision relating to any other course if treatment. After all,

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[3] For the same reason, to the extent that Ideus claims the direct consumer marketing exception to the learned intermediary doctrine applies, *see Rimbert v. Eli Lilly and Co.*, 577 F. Supp. 2d 1174 (D.N.M. 2008), that argument has no merit. If anything, it further supports the Court's conclusion the contraceptives and other prescription drugs are not actually distinguishable. *See generally Rimbert*, 577 F. Supp. 2d at 1219 (anti-depressant marketed to general public) ; *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 782 (S.D. Tex. 2008), *aff'd*, 321 F. App'x 350 (5th Cir. 2009) (antipsychotic medication marked to general public).

> [t]he fact that the patient makes the final choice among suggested contraceptives (or decides not to use any at all) does not constitute a distinction which makes the [learned intermediary] rule inapplicable. [The Court] can readily conceive of situations in which a physician gives the patient a choice of courses to follow. There is, for example, a patient's choice between continuing to endure a physical ailment or submitting to surgery or some other course of treatment; an obese person's choice among diets suggested by the doctor; and a surgery patient's choice of anesthesia where, in the doctor's opinion, a choice is permissible.
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> In any such situation which may come to mind, the patient is expected to look to the physician for guidance and not to the manufacturer of the products which he may use or prescribe in the course of treatment.

Terhune, 577 P.2d at 978. That logic is particularly true here.

In sum, the Court concludes that this case is distinguishable from *Hill*. More broadly though, whatever differences there may be between contraceptives and "typical" prescription drugs, they have one important thing in common: both are *always* prescribed by a physician or through the services of a physician. And when a patient relies on the skill and knowledge of a physician in any particular method of treatment, the learned intermediary doctrine ought to apply. *See Terhune*, 577 P.2d at 978. This is no less true for prescription contraceptives as for any other prescription medication.

Moreover, the Nebraska Supreme Court not only adopted the learned intermediary doctrine—it expressly adopted the doctrine as stated in the

Restatement (Third) of Torts: Prod. Liab. § 6(d) (1998). *Freeman*, 618 N.W.2d at 571. And that section of the Restatement acknowledges circumstances under which the doctrine might not be applicable: "when reasonable instructions or warnings . . . are not provided to . . . the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." Restatement, § 6(d)(2). There is nothing in the record or the parties' arguments to suggest with respect to contraceptives in general, or Ideus' circumstances in particular, that a health care provider is not in a position to reduce the risk of any foreseeable harm to the patient. In other words, the Nebraska Supreme Court *did* acknowledge the possibility of exceptions to the learned intermediary doctrine, when it expressly adopted § 6(d) of the Restatement—but nothing suggests that such an exception should be recognized here.

Based on the foregoing, the Court determines that if presented with this decision, the Nebraska Supreme Court would following the overwhelming majority of decisions that have applied the learned intermediary doctrine to cases involving contraceptives. *Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992) (IUD); *Beyette v. Ortho Pharm. Corp.*, 823 F.2d 990 (6th Cir. 1987) (IUD); *Gonzalez v. Bayer Healthcare Pharm., Inc.*, 930 F. Supp. 2d 808, 820 (S.D. Tex. 2013) (IUD); *In Re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Prod. Liab. Litig.*, 692 F. Supp. 2d 1025 (S.D. Ill. 2010) (oral contraceptive); *In re Norplant Contraceptive Prod. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997), *aff'd sub nom. In re Norplant Contraceptive Prod. Litig.*, 165 F.3d 374 (5th Cir. 1999) (Norplant contraceptive); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991) (oral contraceptive); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 (D. N.J. 1988) (IUD); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1304 (D. Minn. 1988) (IUD);

Goodson v. Searle Labs., 471 F. Supp. 546, 549 (D. Conn. 1978) (oral contraceptive); *Chambers v. G.D. Searle*, 441 F. Supp. 377 (D. Md. 1975), *aff'd* 567 F.2d 269 (4th Cir. 1977) (oral contraceptive); *West*, 806 S.W.2d at 614 (IUD); *Cobb*, 444 So. 2d at 203 (La. App. 1983); (oral contraceptive); *McKee*, 648 P.2d at 21-23 (IUD); *Seley*, 423 N.E.2d at 831 (oral contraceptive); *Chapman*, 388 N.E.2d at 541 (oral contraceptive); *Terhune*, 577 P.2d at 978 (IUD); *McEwen*, 528 P.2d at 523 (oral contraceptive); *Leibowitz*, 307 A.2d at 450 (oral contraceptive).

In Nebraska, a plaintiff's claim is barred under the learned intermediary doctrine if adequate warnings were given to the plaintiff's health care provider. *See Freeman*, 618 N.W.2d at 842; *see also Vallejo v. Amgen, Inc.*, 8:14-CV-50, 2014 WL 4922901, at *3 (D. Neb. Sept. 29, 2014). As noted above, the learned intermediary doctrine, very generally, shifts the focus from the warnings given directly to the patient (*i.e.*, the patient brochure), to the warnings given to the plaintiff's prescribing physician (*i.e.*, the package insert). That means, when a physician has actual knowledge of the dangers and would have taken the same course had warnings been communicated, the doctor's independent knowledge breaks the causal link, and the plaintiff cannot recover. *See generally Freeman,* 618 N.W.2d at 842; *Hammond v. Nebraska Nat. Gas Co.*, 281 N.W.2d 520, 524 (Neb. 1979); *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 300 (8th Cir. 1996); *Strong v. E. I. DuPont de Nemours Co.*, 667 F.2d 682, 688 (8th Cir. 1981); (applying Nebraska law); *see also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) (applying Missouri law); *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 256 (5th Cir. 1999).

So, to avoid summary judgment, Ideus must demonstrate that had the package insert contained a different warning, the treating physician would not have used or prescribed ParaGard. *See Freeman,* 618 N.W.2d at 842*; Brinkley,*

772 F.3d at 1138. But here, there is no evidence to suggest that Ideus' physician would not have inserted ParaGard had the warnings in the package insert been stronger or more specific. In fact, Ideus has not even named the physician who prescribed and placed her IUD—much less demonstrated that had that physician been given the proper warning, she would not have placed ParaGard. *See Freeman*, 618 N.W.2d at 842; *Brinkley*, 772 F.3d at 1138; filing 95 at 19. And without any evidence before the Court demonstrating that Ideus' prescribing physician would have changed her prescribing decision if different warnings had been given, Ideus cannot carry her burden of demonstrating proximate cause. *Freeman*, 618 N.W.2d at 842; *Brinkley*, 772 F.3d at 1138; *see also Estrada v. Teva*, No. 3:14-CV-1875, slip op. at 25-27 (S.D. Cal. Oct. 26, 2017) (unpublished opinion); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001).

More fundamentally though, the package insert expressly warned about the possibility of breakage, embedment, and the difficulties of removing ParaGard, making the warning adequate as a matter of law. *See* filing 91-2 at 5. A warning is adequate if it accurately and unambiguously coveys the scope and nature of the risk to the prescribing physician. *See Freeman*, 618 N.W.2d at 841; *Vallejo*, 2014 WL 4922901, at *3; *Rowland v. Novartis Pharm. Corp.*, 2:12–CV–01474, 2014 WL 3735622, at *12 (W.D. Pa. July 28, 2014); *In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 817 F. Supp. 2d 535, 546 (E.D. Pa. 2011); *see also Felix v. Hoffmann–LaRoche, Inc.*, 540 So. 2d 102, 105 (Fla. 1989).

Here, the package insert clearly stated that "[e]mbedment or breakage of ParaGard in the myometrium can make removal difficult" Filing 19-2 at 12. The label also warned that "[p]artial penetration or embedment of ParaGard in the myometrium can make removal difficult. In some cases, surgical removal

may be necessary." Filing 19-2 at 5. And as Teva's experts opined, in the medical community, that warning is clearly adequate. *Scelta v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 404 F. App'x. 92, 94 (8th Cir. 2010) (in the prescription drug arena, expert medical testimony is needed to determine whether the drug manufacturer's warning to the medical community is adequate); *see also Rowland*, 2014 WL 3735622, at *12.

Specifically, Daniel Davis, M.D., a Board-Certified Obstetrician/ Gynecologist, concluded that "[t]he risks of embedment, breakage (including breakage upon removal), difficult removals and surgery were properly and adequately described in the ParaGard labeling in effect" at the time Ideus' ParaGard was placed. Filing 84-2 at 7. And Sonja R. Kinney, M.D., faculty physician at the University of Nebraska Medical Center in the Department of Obstetrics & Gynecology, also opined that "the instructions and warnings in that ParaGard labeling adequately warned about the possible risks of embedment, breakage of the ParaGard, and surgical removal, including an embedded arm breaking on removal of the ParaGard." Filing 85 at 4.

And Ideus has not come forward with any evidence to dispute those conclusions: she has neither submitted testimony of her own expert challenging the opinions of Dr. Davis and Dr. Kinney, nor has she pointed the Court to any medical literature suggesting ParaGard's warnings might not be adequate. *See Scelta*, 404 F. App'x. at 94; *Rowland*, 2014 WL 3735622, at *12. Instead, Ideus generally argues that because there are numerous reports of breakage and embedment, the ParaGard warnings were necessarily "ambiguous and incomplete." Filing 96 at 33. But that evidence does not demonstrate how the actual warnings given were inadequate—it only proves that the risks warned against actually occurred with some frequency. *See* filing 90 at 6-11. Nor is the Court persuaded by Ideus' contention that the ParaGard

warnings are suddenly inadequate because the package insert did not specifically warn that "ParaGard could break during removal or that it could be broken before removal if the threads could be found." *See* filing 96 at 33. Any distinction as to when precisely ParaGard could break, or whether the threads could be found before removal, does not in any way diminish the warnings actually given. And despite Ideus' assertions, the prescribing physician was warned of the exact scenario at issue here: that embedment and breakage can make removal difficult, and in some instances, surgery may be required to remove ParaGard. *See* filing 57 at 5.

In sum, based on the evidence before it, the Court concludes that there can be no genuine dispute of as to the adequacy of the ParaGard warning. *See Freeman*, 618 N.W.2d at 841; *Vallejo*, 2014 WL 4922901, at *3; *Scelta*, 404 F. App'x. at 94; *Rowland*, 2:12–CV–01474, 2014 WL 3735622, at *12. As such, the learned intermediary doctrine cuts off Teva's liability. Teva's motion for summary judgment will be granted and Ideus' complaint will be dismissed.

IT IS ORDERED:

1. Teva's motion for summary judgment (filing 81) is granted.

2. Gleaves' second amended complaint (filing 57) is dismissed.

3. A separate judgment will be entered.

Dated this 19th day of February, 2019.

BY THE COURT:

John M. Gerrard
Chief United States District Judge